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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1746	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/692,088	WOOD ET AL.	
	Examiner	Art Unit	
	Sharidan Carrillo	1746	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-19 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for saline solutions, organic solvents, deionized water, buffered aqueous solutions, does not reasonably provide enablement for any second liquid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims embrace an invention which contains any known second liquid, which could/can be selected from literally thousands. It does not appear to be feasible that any liquid would function for cleaning contact lens. Further, for one skilled in the art to reproduce the present invention (which must be possible, if the specification is adequate), there would clearly be undue experimentation to do so to determine which liquids work and which ones do not for cleaning of contact lenses.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations of shrinking the swollen contact lens to within 5% of the functional size constitute new matter, no supported by the specification as originally filed. Specifically, paragraphs 6, 9, 19 and 32 teaches shrinking the contact lens back to "its function size". The specification does not teach shrinking to "within 5% of the functional size". Therefore, the limitations constitute new matter.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

6. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the preamble recites a method of removing excess material, however the claim fails to recite a positive step of removing excess material. Additionally, it is unclear what the excess material is since there is no positive limitation recited in the claim. Claim 1 is indefinite because it is unclear what one of ordinary skill in the art would consider as 5% or larger than the functional size or within 5% of the functional size. Applicant argues that the specification teaches the functional size as the size of the lens when the lens is sold to the end-user. However, although the specification teaches that the functional size is the size of the lens sold to the end-user, it is still unclear what that size is. Since the size of the lens sold to the end-user is not

known and the specification fails to provide any further examples of the size, it is unclear what one would consider as 5% or larger than the functional size or within 5% of the functional size. Additionally, since manufacturers may make contact lens of different sizes and or thickness, the functional size may not be the same. Therefore, the claim is further rendered indefinite. Claims 4-5 are indefinite because it is unclear how the first liquid can have a greater ionic strength than the second liquid if both the first and the second liquid are the same solution (i.e. buffered aqueous solution). Claim 6 is indefinite because "salt solution" lacks positive antecedent basis. Claims 18-19 are indefinite because it is unclear what is meant by "HEMA".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Driscoll et al. (3829329).

O'Driscoll teaches a method of cleaning contact lenses. In reference to claim 1, O'Driscoll teaches swelling the contact lens with a 0.9% NaCl solution followed by shrinking with hydrogen peroxide (col. 9, lines 53-58). In reference to claims 2-7, refer to Fig. 3. In reference to claim 9, refer to col. 10, lines 24-33. In reference to claim 11, refer to col. 1, lines 30-33. In reference to claim 12, Fig. 3 teaches osmotic swelling for 4 hours. In reference to claim 13, Fig. 3 teaches 200F, which is equivalent to 93C. In reference to claim 18, refer to col. 5, lines 5-7, 60-63.

O'Driscoll fails to teach swelling contact lens that is 5% or larger than the functional size or shrinking lens within 5% of the functional size. However, one would reasonably expect swelling to be 5% or greater since O'Driscoll teaches expanding the core diameter of the lens to 35% and thickness to 23%. Additionally, paragraph 11 of the instant specification teaches swelling to include 10-60% of water content. O'Driscoll

teaches swelling the lens to include a water content of 40-80%. Therefore one would reasonably expect the swelling of O'Driscoll to increase to at least 5% increase of the functional size. One would reasonably expect shrinkage to be within 5% of the functional size since O'Driscoll teaches reversing the effects of swelling using a 3% hydrogen peroxide solution. Additionally, in view of the indefiniteness with respect to the functional size, as described above, the limitations are met by the teachings of O'Driscoll.

In reference to claim 8, O'Driscoll fails to teach the difference in ionic strength. However, it would have been obvious to a person of ordinary skill in the art to modify the method of O'Driscoll to include a difference in ionic strength in order to cause the swelling and shrinking of the contact lens. In reference to claim 10, O'Driscoll fails to teach expanding the core diameter by at least about 1mm. However, it would have been within the level of the skilled artisan to modify the method to include increasing the diameter to 1mm since O'Driscoll teaches that the core diameter expands to 35% and the thickness expands to 23%.

11. Claims 1-3 and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayyagari et al. (WO01/45868A1).

Ayyagari teaches a method of pulsed extraction of residual materials from contact lenses. Ayyagari teaches varying the concentration of the primary solvent and a co-solvent. As the amount of co-solvent increases, the lens swell. As the amount of co-solvent reduces, the lens shrink. Ayyagari teaches pulsed extraction cycle in which the co-solvent (IPA) begins at a lower first amount and then is increased to a second higher

amount (swelling with 20%IPA) and then is returned to the lower first amount (shrinking with 5%IPA). During each pulse, the lens goes through one cycle of expansion and shrinkage. Claims 2-3 are met as a result of increasing the concentration of IPA during the swelling step. The limitations of claim 7 are met since Ayyagari teaches using an aqueous solution of IPA. In reference to claim 9, Table 1 shows varying degrees of expansion as a result of varying concentrations of IPA. In reference to claim 10, the limitations are met since Ayyagari teaches expanding the lens to 79% (Table 1). In reference to claim 11, refer to Table 1. In reference to claim 12, refer to page 9, Fig. 3. In reference to claim 13, refer to page 8. In reference to claim 14, refer to page 11. In reference to claims 15-16, the limitations are met since Ayyagari teaches that diluents need to be extracted from the contact lens and further teaches extracting in a series of steps using supercritical fluid in combination with IPA. It is the combination of all of the extraction steps which result in the removal of diluents from the lens. Therefore, the limitations are met by Ayyagari.

Ayyagari fails to teach swelling that is 5% or larger than the functional size or shrinking the lens within 5% of the functional size. However, one would reasonably expect swelling to be 5% or greater than the functional size since Ayyagari teaches expanding the lens as the concentration of IPA increases and shrinking the lens back to its original state as the IPA concentration increases. Additionally, in view of the indefiniteness with respect to the functional size, as described above, the limitations are met by the teachings of Ayyagari.

In reference to claim 8, Ayyagari fails to teach the difference in the ionic strength. However, it would have been obvious to a person of ordinary skill in the art to modify the method of Ayyagari to include a difference in ionic strength in order to cause the swelling and shrinking of the contact lens. In reference to claim 17, Ayyagari fails to teach contact lens which are tinted. However, it would have been within the level of the skilled artisan to include tinted lenses since Ayyagari teaches that any type of lens can be used for the extraction process.

12. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayyagari et al. (WO01/45868A1) in view of Qui et al. (2004/018295).

Ayyagari fails to teach the limitations of claims 18-19. Qui et al. teaches swelling and shrinking of contact lens (paragraphs 196-197). In paragraph 102, Qui teaches it is conventional in the art to manufacture biomedical devices (such as contact lenses) with materials made of Elastofilcon. It would have been obvious to a person of ordinary skill in the art to modify the method of Ayyagari to include Elastofilcon, as taught by Qui, which are used conventionally in the manufacture of contact lenses.

Response to Arguments

13. The rejections of the claims, under 112, first paragraph and second paragraph, are maintained for the reasons set forth above.

14. The rejections of the clams as being anticipated by O'Driscoll or Ayyagari are withdrawn in view of the newly amended claims. A new grounds of rejection has been introduced, as described above.

15. Applicant argues that O'Driscoll or Ayyagari fails to teach swelling that is larger than 5% of its functional size. Although O'Driscoll or Ayyagari do not specifically recite the percentage of swelling and shrinking, applicant's arguments are not persuasive for the reasons, as previously recited in paragraphs 10-11 above.

16. Applicant argues that O'Driscoll fails to teach the claimed liquid. Applicant's arguments are unpersuasive because O'Driscoll teaches deionized water and a saline solution.

17. Applicant argues that Ayyagari teaches against significant swelling. What exactly would one consider as "significant swelling". Page 10 of Ayyagari teaches expanding the contact lens in order to extract contaminants. Applicant further argues that Ayyagari fails to teach the claimed liquid. Ayyagari teaches the aqueous IPA solution which reads on the claimed limitations.

18. Applicant argues that Qui et al. fail to teach swelling to a size that is 5% larger of the functional size and shrinking back to within 5%. The secondary reference of Qui et al. is relied on to teach conventional materials used in the manufacture of contact lens. The primary reference of Ayyagari is relied upon to cure the above deficiency.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 571-272-1297. The examiner can normally be reached on Monday-Wednesday, 6:00a.m-3:30pm and alternating Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharidan Carrillo
Primary Examiner
Art Unit 1746

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